

II. Claims 2-3, 7, 9, 14-16 and 18 are Cancelled

Claim 2-3, 7, 9, 14-16 and 18 are hereby cancelled without prejudice to further prosecution at a later date.

III. Rejection of Claims 1-25 under 35 U.S.C. § 112, First Paragraph

The Office Action rejected claims 1-25 under 35 U.S.C. §112, first paragraph on the basis that the specification does not enable the present claims, but that it does enable the claimed method with (1) use of a botulinum toxin; (2) administered to specific brain locations; (3) in specified amounts with; (4) a determined outcome.

All the claims have been amended to a clearly enabled claim scope and the rejection should therefore be withdrawn.

Thus:

(1) "neurotoxin" has been amended to "botulinum toxin"

(2) the claims are limited to the specific brain locations of the hypothalamus or pituitary. Applicant's invention is not limited to the administration of a botulinum toxin to a particular intrahypothalamic or intrapituitary nuclei or foci, as the particular hypothalamic or pituitary location selected for botulinum toxin administration depends upon the particular endocrine condition to be treated. Known mapping of the locations of hypothalamic and pituitary sites responsible for the secretion of particular hormone or releasing hormone in conjunction with stereotactic techniques permits the person of ordinary skill practicing the claimed invention (i.e. a neurosurgeon) to select with submillimeter precision the appropriate location or locations for botulinum toxin administration, depending upon the hormone or releasing hormone to be affected, as determined by the endocrine condition to be treated. Hence, the person of ordinary skill is able to determine without undue experimentation the particular hypothalamic or pituitary location to which to administer the botulinum toxin according to the claimed invention. Thus, it would deny applicant the full scope of his invention to which he is entitled and unnecessary for the practise of the claimed invention to require

further limitation as to the intracranial location to which the botulinum toxin is to be administered.

(3) as suggested on page 4 of the Office Action, all claims have been limited to a "therapeutically effective amount" of the botulinum toxin.

(4) all claims, as amended, are limited to the determined outcome of reduction of a hormone or releasing hormone secretion from the hypothalamus or pituitary.

The claims have been amended to treatment of an "endocrine condition" as opposed to the formerly claimed "endocrine disorder". This is warranted since all the particular endocrine conditions set forth by the Examples in the specification (gametogenesis, menstruation, acromegaly, gigantism, Cushing's disease, hypergonadism and hyperthyroidism) have been set forth in the express enumeration in the claims of the particular conditions to be treated by the claimed method.

For these reasons the rejection should be withdrawn.

IV. Rejection of Claim 5

Claim 5 was rejected claim 5 under 35 U.S.C. § 112, second paragraph. Claim 5 has been amended to remove the basis for the rejection. Hence, the rejection should be withdrawn.

V. Rejection of Claims 1 and 7 under 35 U.S.C. § 102(b)

The Office Action rejected claims 1 and 7 under 35 U.S.C. § 102(b) as being anticipated by Monti. Monti discloses use of atropine. All claims, as amended, are limited to use of a botulinum toxin. Monti does not teach or suggest use of a botulinum toxin. Hence, the rejection should be withdrawn.

VI. Rejection of Claims 1-4, 6, 9-10, 13 and 15

under 35 U.S.C. § 103(a)

The Office Action rejected claims 1-4, 6, 9-10, 13 and 15 under 35 U.S.C. § 103(a) as being unpatentable over Jacobsson in view of Andrews.

Jacobsson discusses administration of a botulinum toxin type F *in vitro* to cultured rat pituitary cells. The cells were permeabilized to facilitate entry of the type F toxin into the cells.

The claimed invention excludes use of botulinum toxin type F. Additionally, the claimed invention is practised *in vivo* to humans, not to rats, not upon any cultured cells and not upon any permeabilized cells.

Hence, the combination of Jacobsson and Andrews cannot teach or suggest the claims, as amended, and the rejection should therefore be withdrawn.